

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mark A. Burns et al.

Serial No.:

09/751,493

Group No.: Examiner:

1634

Sisson, B.

Filed: Entitled: 12/28/00 Microscale Devices And Reactions In Microscale

Devices

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Dated: May 20, 2003

By:

Christopher . Collins

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: May 20, 2003

Carròll Peterl G.

Registration No. 32,837

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105

617/252-3353



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Dated: May 20, 2003

Bv

Christopher J. C

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications were incorporated by reference in the body of the specification:

- U.S. Patent No. 4,683,195 to Mullis et al.;
- U.S. Patent No. 4,683,202 to Mullis et al.;
- U.S. Patent No. 5,091,328 to W. Miller;
- Marmur and Lane, "Strand Separation and Specific Recombination in Deoxyribonucleic Acids: Biological Studies", *Proc.Nat.Acad.Sci.*, *U.S.A.* 46:453-461 (1960);

- Doty et al., "Strand Separation and Specific Recombination in Deoxyribonucleic Acids: Physical Chemical Studies", Proc. Nat. Acad. Sci., U.S.A. 46:461-477 (1960);
- Hayashi et al., "Restriction of in Vivo Genetic Transcription to one of the Complementary Strands of DNA", Proc.Nat.Acad.Sci., U.S.A. 50: 664-671 (1963);
- Smith and Wilcox, "A Restriction Enzyme from *Hemophilus influenzae*", *J.Mol.Biol.* 51:379-391 (1970);
- Southern, "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis", *J. Mol. Biol.* 98:503-517 (1975);
- Maxam and Gilbert, "A new method for sequencing DNA", *Proc. Natl. Acad Sci. USA* 74:560-564(1977);
- Sanger et al., "DNA sequencing with chain-terminating inhibitors", Proc. Natl. Acad Sci. USA 74:5463-5467 (1977);
- R. Gomer and R. Firtel, "Sequencing homopolymer regions." Bethesda Res. Lab. Focus 7:6 (1985);¹
- S. Karanthanasis, "M13 DNA sequencing using reverse transcriptase" Bethesda Res. Lab. Focus 4(3):6 (1982);²
- Graham et al., "Direct DNA sequencing using avian myeloblastosis virus and Moleney murine leukemia virus reverse transcriptase" Bethesda Res. Lab. Focus 8(2):4 (1986);
- Sambrook, J. et al. Molecular Cloning, A Laboratory Manual, 2d Ed. Cold Spring Harbor Laboratory Press, New York, 13.7-13.9;
- Hunkapiller, M.W., "Advances in DNA sequencing technology", Curr. Op.
 Gen. Devl. 1:88-92 (1991);
- Tabor et al., "DNA sequence analysis with a modified bacteriophage T7 DNA polymerase", Proc. Natl. Acad. Sci. USA 84:4767-4771 (1987);

We have attempted to obtain this reference and as yet have not been able to. If the examiner so requests, we can increase our efforts to obtain this reference.

We have attempted to obtain this reference and as yet have not been able to. If the examiner so requests, we can increase our efforts to obtain this reference.

- Innis et al., "DNA sequencing with *Thermus aquaticus* DNA polymerase and direct sequencing of polymerase chain reaction-amplified DNA", *Proc. Natl. Acad. Sci. USA* 85:9436-9440 (1988);
- J. Pfahler et al., "Liquid Transport in Micron and Submicron Channels", Sensors and Actuators A21-A23: 431-434 (1990); and
- H.T.G. Van Lintel et al., "A Piezoelectric Micropump Based on Micromachining of Silicon", Sensors and Actuators 15:153-167 (1988).

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- Smits, "Piezoelectric Micropump with Three Valves Working Peristaltically,"

 Sensors and Actuators A21-A23:203 (1990) describe a silicon micropump that can be used to pump liquids or gases to a higher pressure, which can then be relieved through a check valve. The device is intended for use in constant rate delivery of drugs for pain relief or diabetes, cryogenic coolant pumps, etc.

 There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Mullis and Faloona, "Specific Synthesis of DNA in Vitro via a Polymerase-Catalyzed Chain Reaction," Meth. Enzym. 155:335 (1987) describe a method for the synthesis of DNA utilizing a template, primer and DNA polymerase. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Arnheim, "Polymerase Chain Reaction Strategy," Annu. Rev. Biochem. 61:131
 (1992) describe methods and strategies for utilizing the Polymerase Chain
 Reaction. There is no discussion of a fluid transport channel, wherein a series
 of heating elements are configured to provide differential heating.
- Nickerson et al., "Automated DNA diagnostics using an ELISA-based oligonucleotide ligation assay," Proc. Nat. Acad. Sci. USA 87:8923 (1990) describe a method of DNA diagnostics using amplification of target DNA segments by PCR and discrimination of allelic sequence variants by a colorimetric oligonucleotide ligation assay. There is no discussion of a fluid

- transport channel, wherein a series of heating elements are configured to provide differential heating.
- Gordon *et al.*, "Capillary Electrophoresis," *Science* 27:224 (1988) describe a method of separation of molecules in solution in a capillary tube. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Lawrence Berkeley Lab Presentation, Park City, Utah (1993) describes a micro-PCR device. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Turner, "New Dimensions in Capillary Electrophoresis Columns," LC-GC vol. 9 (1991) describes various methods of capillary electrophoresis, including rectangular tubing, wall-coated capillary columns and capillary gel electrophoresis. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Heller and Tullis, "Microelectrophoresis for the separation of DNA fragments," Electrophoresis 13:512 (1992) describe separation of DNA fragments and oligonucleotides in microscopic bands in either capillary tube or thin-layer microgel formats of one centimeter or less in length. Bands are detected using high-resolution electronic imaging systems. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Manz et al., "Planar chips technology for miniaturization and integration of separation techniques into monitoring systems Capillary electrophoresis on a chip," J. Chrom. 593:253 (1992) describe miniaturization of capillary electrophoresis on a microchip. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Jorgenson and Lukacs, "High-Resolution Separations Based on Electrophoresis and Electroosmosis," *J. Chrom.* 218:209 (1981) describe capillary electrophoresis in a 75 micrometer glass capillary and reverse phase chromatography in the same apparatus. Electroosmotic pumping is utilized for

- acetonitrile mobile phase. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Ansorge et al., "High-throughput automated DNA sequencing facility with fluorescent labels at the European Molecular Biology Laboratory,"

 Electrophoresis 13:616 (1992) describe a facility for automated on-line DNA sequencing for maximum throughput of gel sequencing technology. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- high performance capillary electrophoresis," *Electrophoresis* 13:467 (1992) describe the use of laser induced fluorescence detection for enzymatic chain termination sequencing of DNA using high performance capillary gel electrophoresis. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Daniel et al., French patent #2,672,301, 7-8-92, describes continuous and discontinuous flow (page 19). There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Tenan et al., "Friction in Capillary Systems," Journal of Applied Physics 53:6687 (1982), describe contact angle hystersis as requiring a threshold pressure difference for positive motion. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Dussan, "On the Spreading of Liquids on Solid Surfaces Static and Dynamic Contact Lines," Annual Review of Fluid Mechanics 11:371 (1979) quantitatively describes the physical parameters of static and dynamic contact angles. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- Probstein, "Physicochemical Hydrodynamics," (1989), describes how a pressure difference occurs across the liquid-air interface in channels which is a function

- of surface tension. There is no discussion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.
- U.S. Patent No. 4,829,324 to Drake *et al.*, describes an ink jet printhead made primarily of silicon and comprising heating elements. There is no suggestion of a fluid transport channel, wherein a series of heating elements are configured to provide differential heating.

The following references discuss the present invention and were published less than one year prior to the priority date of this application. They are being provided for the convenience of the examiner.

- R.F. Service, "The Incredible Shrinking Laboratory," Science 268:26 (1995),
 while it does not directly address the present invention, presents brief
 discussion of the impact of microinstruments on the future of laboratory
 research.
- Presentation at Cold Spring Harbor (August 31-September 2, 1995) describes a micro-PCR device.
- R. Nowak, "Xeroxing DNA Analysis," describes the excitement that is induced by the possibility of a device as disclosed in the present invention.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 20, 2003

Peter

Registration No. 32,837

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 617/252-3353

FORM PTO-1449 (Modified)

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rney Docket No.: UM-04985

Serial No.: 09/751,493

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)

Applicant: Mark A. Burns et al.

Group Art Unit: 1634 Filing Date: 12/28/00

37 CFR § 1.9	8(b))				Filing Date: 12/28/0	0	Group Art Uni	it: 1634		
3				U.S. PATENT DOC	CUMENTS					
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applic	ant / Patentee	Class	Subclass	Filing	Date	
	1	4,683,195	07/28/87	Mı	ullis <i>et al</i> .	435	6	02/0	7/86	
	2	4,683,202	07/28/87	Mı	ullis et al.	435	91	10/2:	5/86	
	3	5,091,328	02/25/92	v	V. Miller	437	52	11/2	1/89	
	4	4,829,324	5/09/89	Dr	rake et al.	346	140	12/23/87		
		FO	OREIGN PATENTS (OR PUBLISHED FO	REIGN PATENT APPI	LICATIONS	T	I	_	
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	5	2672301	8/1992		FR					
		OTHER	DOCUMENTS (Inclu	iding Author, Title, I	Date, Relevant Pages, Pl	lace of Publication)				
	6	Marmur and Lane, "Strand Separation and Specific Recombination in Deoxyribonucleic Acids: Biological Studies," <i>Proc.Nat.Acad.Sci.</i> , U.S.A. 46, 453 (1960)								
	7	Doty et al., "Strand Separation and Specific Recombination in Deoxyribonucleic Acids: Physical Chemical Studies," Proc.Nat.Acad.Sci., U.S.A. 46, 461 (1960)								
	8	Hayashi et al., "Restriction of in Vivo Genetic Transcription to one of the Complementary Strands of DNA," Proc.Nat.Acad.Sci., U.S.A. 664 (1963)							S.A. 5	
	9	Smith and Wilcox, "A Restriction Enzyme from Hemophilus influenzae," J.Mol.Biol. 51, 379 (1970)								
	10	Southern, "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis," J.Mol.Biol. 98, 503 (1975)								
	11	Maxam and Gilbert, "A new method for sequencing DNA," Proc. Natl. Acad Sci. USA 74:560 (1977)								
	12	Sanger et al., "DNA sequencing with chain-terminating inhibitors," Proc. Natl. Acad Sci. USA 74:5463 (1977)								
	Graham et al., "Direct DNA sequencing using avian myeloblastosis virus and Moleney murine leukemia virus reverse trans Res. Lab. Focus 8(2):4 (1986)							anscriptase"	Beth	
	14	Sambrook, J. et ac	Molecular Cloning,	A Laboratory Manua	al, 2d Ed. Cold Spring I	Iarbor Laboratory I	Press, New York,	13.7-13.9		
	15	Hunkapiller M.W., "Advances in DNA sequencing technology," Curr. Op. Gen. Devl. 1:88-92 (1991)								
	16				riophage T7 DNA polyi					
Innis et al., "DNA sequencing with Thermus aquaticus DNA polymerase and direct seq DNA," Proc. Natl. Acad. Sci. USA 85:9436 (1988)							merase chain rea	ction-ampli	fied	
	18	J. Pfahler et al., "	Liquid Transport in M	licron and Submicror	n Channels," Sensors an	nd Actuators, A21-A	A23, pp. 431-434	(1990)		
-	19	H.T.G. Van Linte	l et al., "A Piezoelectr	ric Micropump based	on Micromachining of	Silicon," Sensors a	nd Actuators 15:	153-167 (1	988)	
	20	Smits, "Piezoelect	ric Micropump with T	Three Valves Workin	g Peristaltically," Senso	rs and Actuators A	21-A23:203 (199	0)		
	21	Mullis and Faloor	na, "Specific Synthesis	of DNA in Vitro vi	a a Polymerase-Catalyze	ed Chain Reaction,"	Meth. Enzym. 1	55:335 <u>(</u> 19	87)	
	22	Arnheim, "Polyme	erase Chain Reaction	Strategy," Annu. Rev	v. Biochem. 61:131 (199	92)				
	23	Nickerson <i>et al.</i> , (1990)	"Automated DNA diag	gnostics using an EL	ISA-based oligonucleoti	ide ligation assay,"	Proc. Nat. Acad.	Sci. USA	37:892	
	24	Gordon et al., "C	apillary Electrophoresi	is," Science 27:224 ((1988)					
	25	Lawrence Berkele	ey Lab Presentation, P	Park City, Utah (1993	3)			1		

Examiner:

Date Considered:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. EXAMINER:

FORM PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.: UM-04985

Applicant: Mark A. Burns et al.

Serial No.: 09/751,493

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)

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7 CFR § 1.98(<u>((</u>	OTHER DOCUMENTS (Including Author, Title, D	ate, Relevant Pages, Place of Publication)						
	26	Turner, "New Dimensions in Capillary Electrophoresis Column							
	27	Heller and Tullis, "Microelectrophoresis for the separation of DNA fragments," Electrophoresis 13:512 (1992)							
	28	Manz et al., "Planar chips technology for miniaturization and integration of separation techniques into monitoring systems Capillary electrophoresis on a chip," J. Chrom. 593:253 (1992)							
	29	Jorgenson and Lukacs, "High-Resolution Separations Based on Electrophoresis and Electroosmosis," J. Chrom. 218:209 (1981)							
Ansorge et al., "High-throughput automated DNA sequencing facility with fluorescent labels at the European Mol Laboratory," Electrophoresis 13:616 (1992)									
	31	Pentoney et al., "A single-fluor approach to DNA sequence determination using high performance capillary electrophoresis," Electrophoresis 13:467 (1992)							
	32	Tenan et al., "Friction in Capillary Systems," Journal of Applied Physics 53:6687 (1982)							
	33	Dussan, "On the Spreading of Liquids on Solid Surfaces Static and Dynamic Contact Lines," Annual Review of Fluid Mechanics 11:371 (1979)							
	34	Probstein, "Physicochemical Hydrodynamics," (1989)							
	35	R.F. Service, "The Incredible Shrinking Laboratory," Science 268:26 (1995)							
	36	Presentation at Cold Spring Harbor (August 31-September 2, 1995)							
	37	R. Nowak, "Xeroxing DNA Analysis" pp. 1135							
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